

# PATENT COOPERATION TREATY

REC'D 03 JUN 2005

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From the  
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/GB2005/000189

International filing date (day/month/year)  
20.01.2005

Priority date (day/month/year)  
20.01.2004

International Patent Classification (IPC) or both national classification and IPC  
C08G18/76, C08G18/44, C08G18/46, C08G18/38, A61L27/18

Applicant  
UCL BIOMEDICA PLC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1 bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:  
☐ a sequence listing  
☐ table(s) related to the sequence listing
  - b. format of material:  
☐ in written format  
☐ in computer readable form
  - c. time of filing/furnishing:  
☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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**Box No. II    Priority**

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1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. ☐ The International Searching Authority has not been able to consider the validity of the priority claim because a copy of the earlier application whose priority has been claimed was not available to the International Searching Authority at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

4. Additional observations, if necessary:

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 1-37 (part)

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 1-37 (part)

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See separate sheet for further details

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**Box No. IV Lack of unity of invention**

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1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
  - ☐ paid additional fees under protest.
  - ☒ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
  - ☒ not complied with for the following reasons:  
**see separate sheet**
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
  - ☒ the parts relating to claims Nos. 1-37 (part)

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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	13-20,24,25,27,29,31,32 (part)
	No: Claims	1-12,21-23,26,28,30,33-37 (part)
Inventive step (IS)	Yes: Claims	13-20,24,25,27,29 (part)
	No: Claims	31,32 (part)
Industrial applicability (IA)	Yes: Claims	1-35 (part), 37 (part)
	No: Claims	36 (part)

2. Citations and explanations

**see separate sheet**

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**Box No. VI    Certain documents cited**

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1. Certain published documents (Rules 43*bis*.1 and 70.10)  
and /or
2. Non-written disclosures (Rules 43*bis*.1 and 70.9)  
**see form 210**

Reference is made to the following documents:

- D1: WO 02/098477 A (SANTERRE, PAUL, J) 12 December 2002 (2002-12-12)
- D2: FU B X ET AL: "Structural development during deformation of polyurethane containing polyhedral oligomeric silsesquioxanes (POSS) molecules" POLYMER, ELSEVIER SCIENCE PUBLISHERS B.V, GB, vol. 42, no. 2, January 2001 (2001-01), pages 599-611, XP004216943 ISSN: 0032-3861
- D3: SCHWAB J J ET AL: "POLYHEDRAL OLIGOMERIC SILSESQUIOXANES (POSS): SILICON BASED MONOMERS AND THEIR USE IN THE PREPARATION OF HYBRID POLYURETHANES" MATERIALS RESEARCH SOCIETY SYMPOSIUM PROCEEDINGS, MATERIALS RESEARCH SOCIETY, PITTSBURG, PA, US, vol. 519, 13 April 1998 (1998-04-13), pages 21-27, XP009040983 ISSN: 0272-9172
- D4: EP-A-0 324 946 (DAINICHISEIKA COLOR & CHEMICALS MFG. CO. LTD; UKIMA COLOUR & CHEMICALS) 26 July 1989 (1989-07-26)
- D5: EP-A-0 277 816 (CHISSO CORPORATION) 10 August 1988 (1988-08-10)
- D6: Q. FAN ET AL.: "Synthesis and Properties of Polyurethane Modified with Aminoethylaminopropyl Poly(dimethyl siloxane)" JOURNAL OF APPLIED POLYMER SCIENCE, vol. 74, 1999, pages 2552-2558, XP002321323

#### **Re Item IV**

#### **Lack of unity of invention**

The present application concerns a copolymer comprising pendant group segments (a) and polyol segments (b), wherein the pendant group segment is selected from siloxane segments (i), phosphoryl choline (derivatives/analogues) containing segments (ii), di- or trifluoromethyl group containing segments (iii), heparin-like segments (iv) and peptide segments according to formula (I)(v) (see claim 1). The common concept of claim 1 is a copolymer comprising pendant group segments (a) and polyol segments (b). This concept is not novel (see for example document D1: claims 1,11-13).



**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement**

**Claims 1-37 (part) - Invention 1: siloxane segments (i)**

**A. Claims 1-35 (part), 37 (part)**

1. Figure 1 of document D2 discloses a polyurethane obtained from a polytetramethylene glycol (corresponds to the polyol segment (b) of the present application), a chain-extender comprising a silsesquioxane cage (corresponds to segment (a)) and an aromatic polyisocyanate.

Therefore document D2 destroys novelty of subject-matter of claims 1-3,6-9,11,12,21,26,28,30,33 (part) of the present application.

2. Figure 4 of document D3 discloses a polyurethane obtained from polytetramethylene glycol (corresponds to the polyol segment (b)) and a chain-extender comprising a silsesquioxane cage (corresponds to segment (a)). An aromatic polyisocyanate can also be used (see page 26, first paragraph).

Therefore document D3 destroys novelty of subject-matter of claims 1-3,6-9,11,12,21,26,28,30,33 (part) of the present application.

3. Examples 3 and 4 of document D4 disclose the preparation of a polyurethane from a linear polysiloxane (corresponds to segment (a)), polybutylene adipate (corresponds to segment (b)), a polyisocyanate and 1,4-butanediol as chain-extender.

Therefore document D4 destroys novelty of subject-matter of claims 1-6,10,11,21-23,26,28,30,33 (part) of the present application.



4. Example 3 of document D5 discloses the preparation of a polyurethane from a linear polysiloxane (corresponds to segment (a)), polytetramethylene ether glycol (corresponds to segment (b)), an aromatic polyisocyanate and 1,4-butanediol as chain extender. The silicone-modified polyurethane can be used as moulding material in the medical field (thrombosis resistance) (see page 7, line 62).

Therefore document D5 destroys novelty of subject-matter of claims 1-6,10,11,21-23,26,28,30,33-35,37 (part) of the present application.

5. Scheme II of document D6 discloses the preparation of a siloxane (linear) -modified polyurethane from poly(tetramethylene oxide), 1,4-butanediol, aminoethylaminopropyl poly(dimethyl siloxane)(AEAPS) and methylene diphenyl diisocyanate (MDI). This polyurethane can be used in medical devices and prostheses (see page 2552, left-hand column).

Therefore document D6 destroys novelty of subject-matter of claims 1-6,10,11,21-23,26,28,30,33-35,37 (part) of the present application.

6. The subject-matter of claims 13-20,24,25,27,29,31,32 is considered to be novel over documents D2-D6. The subject-matter of claims 31,32 deems not to involve an inventive step. The subject-matter of claims 13-20,24,25,27,29 could be considered to involve an inventive step over documents D2-D6.

**B. Claim 36 (part)**

Claim 36 (part) concerns a method of treating of the human or animal body. This claim would not be in agreement with Article 52 EPC.

For the assessment of the present claim 36 (part) on the question whether it is industrially applicable, no unified criteria exist in the PCT Contracting States.

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING  
AUTHORITY (SEPARATE SHEET)**

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Claim 36 (part) relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of this claim (Article 34(4)(a)(I) PCT).

Furthermore the subject-matter of claim 36 (part) deems not to be novel and inventive over documents D5 (see page 7, line 62) and D6 (page 2552, left-hand column).

**Re Item VI**

**Certain documents cited**

**Certain published documents**

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO2004/032799	22.04.2004	10.10.2003	11.10.2002 18.10.2002 29.04.2003 18.07.2003 18.07.2003